



PhUSE 2016 SDE – Deerfield Advanced Clinical

Chris Hurley, US Events Director
Thursday, July 21, 2016



Today's Sponsors – Thank you!



Risk Based Monitoring

Co-Chairs

- Patricia Wozniak, Advanced Clinical
- Edwin Fung, Advanced Clinical

PhUSE Director

- Chris Hurley, MMS Holdings



	Presentation	Speaker
8.30 - 9.00	Welcome Refreshments	
09.00 - 10.00	Advanced Clinical – Welcome & Keynote Overview of Risk-based monitoring and a Case Study of Implementation within a Mid-size CRO	Cheryle Evans, Katie Obermeyer & Patricia Wozniak, <i>Advanced Clinical</i>
10.00 - 10.45	Centralised Statistical Monitoring to Detect Data Integrity Issues	Alun Bedding, <i>AstraZeneca</i>
10.45 - 11.00	Morning Break	
11.00 - 11.30	How Can I Contribute to Risk-based Monitoring? A Statistical Programmers Perspective	Parag Shiralkar, <i>Eliassen Group</i>
11.30 - 11.45	PhUSE Update	Chris Hurley, <i>MMS Holdings</i>
11.45 - 12.45	Lunch	
12.45 - 1.45	Fraud Detection and Runway for RBM	Martin King & Naveen Katta, <i>AbbVie</i>
1.45 - 2.15	Update on Risk-based Site Selection Tool	Susan Thompson, <i>FDA</i>
2.15 - 2.45	The Role of Programmers in Defining and Execution of Trial Specific Reports as Part of Trial Set Up and Execution	Sina Djali, <i>Janssen R&D</i>
2.45 - 3.00	Afternoon Break	
3.00 - 3.30	Strategies for Managing Your Data to Support RBM Workflow	Casey Higgins, <i>Chiltern</i>
3.30 - 4.00	Panel Discussion	All Speakers

2016 Highlights

- 480+ registered so far for Annual Conference
- 313 attended CSS Conference in March
- First ever European CSS
- 18 Single Day Events
- 5 Working Groups with 27 Active WG Projects
- US FDA, EU EMA, Japan PMDA Collaborations
- PhUSE-Industry Future Forum



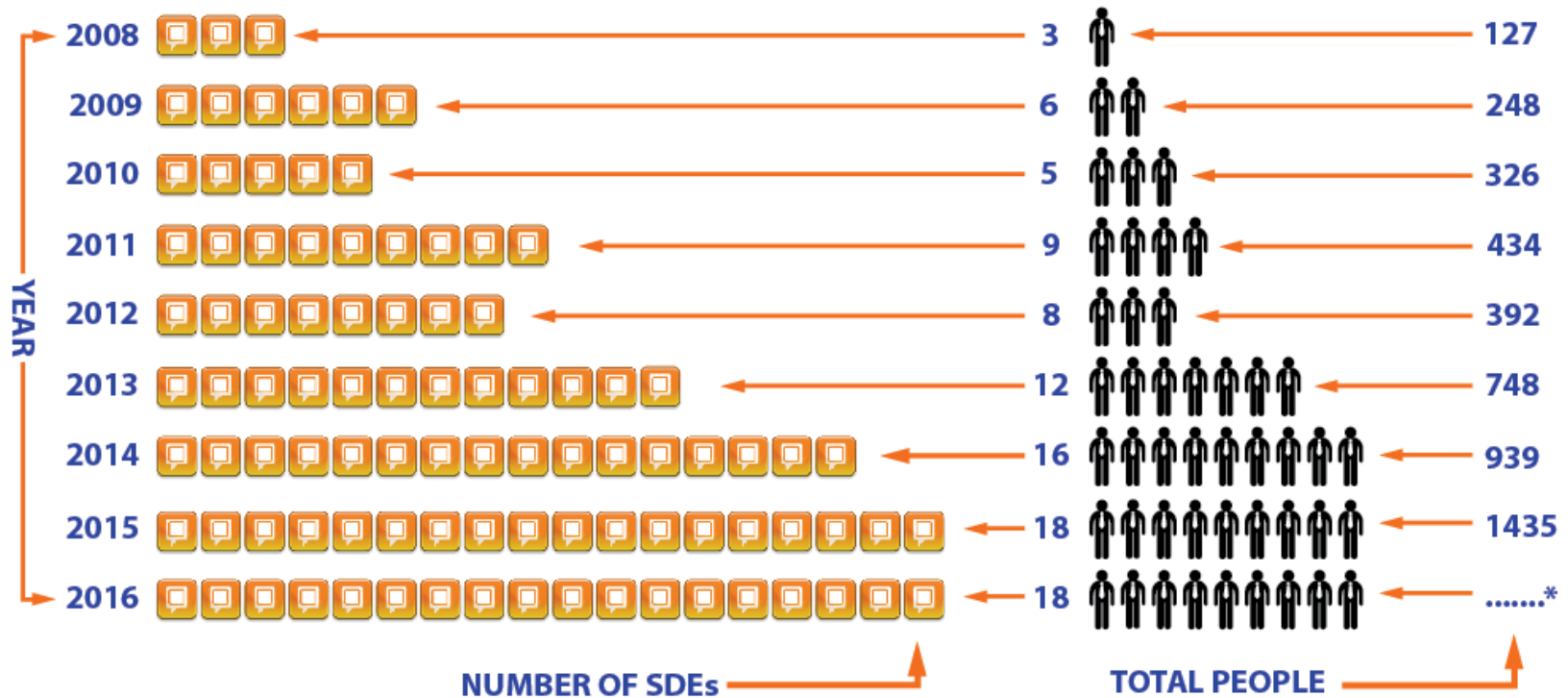
2016 European CSS

- 1st European CSS
 - Basel, Switzerland
 - 102 Attendees
- Webinar Wed, July 27th

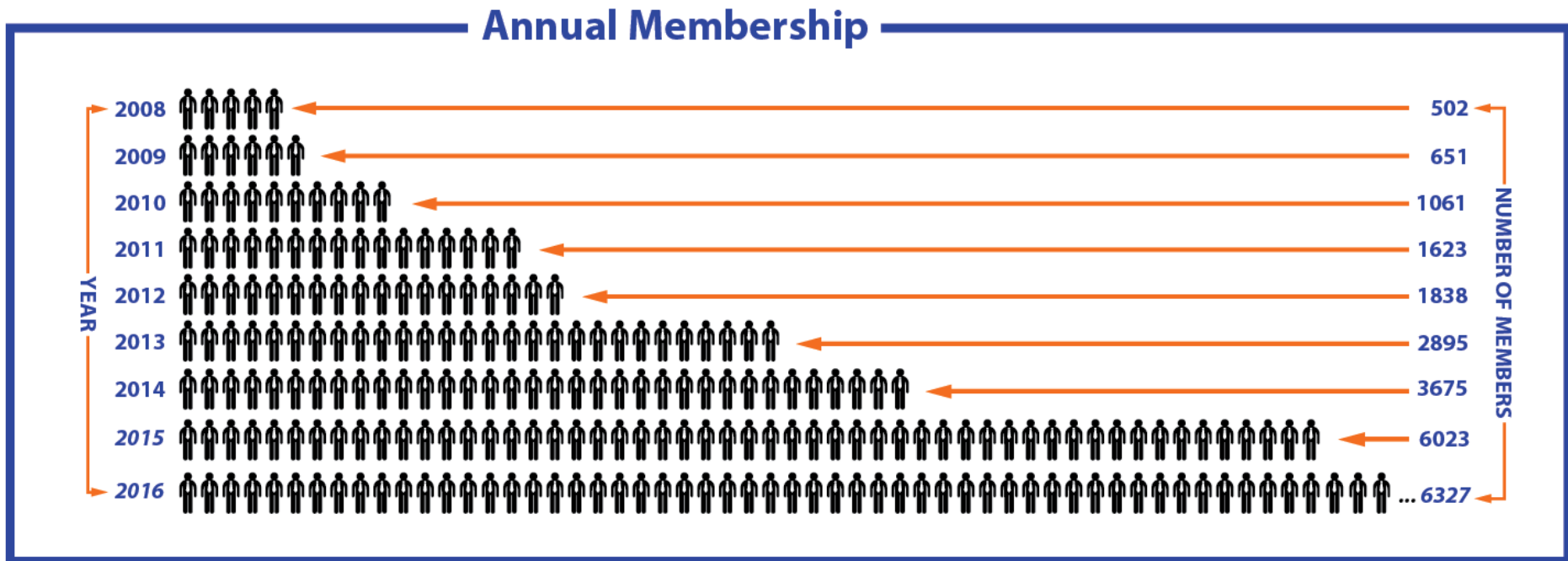
EU CSS 2016 - Basel	Novartis, Basel, Switzerland	21/06/2016 104 102
<u>Options</u>		
Evaluate and Prototype Alternative Transport Formats for Submission		10
Experiences Statistical Computing Environments		24
De-identification of ADaM Datasets		20
Nonclinical Roadmap and Impact on Implementation Working Group		16
SDTM Implementation FAQ		10
PhUSE Future Forum: Process Optimization		18

Global Single Day Events

PhUSE SDEs



World's largest biometrics society



Members as of 21JUL2016 ... 6855!

The new PhUSE App

Stay up to date with everything
going on at PhUSE

Mobile access to:

- News
- PhUSE Tube
- Event Schedule with options to register, add to own calendar, routes, etc.
- Social Media Channels
- ...

The next level to
Share – Contribute - Advance



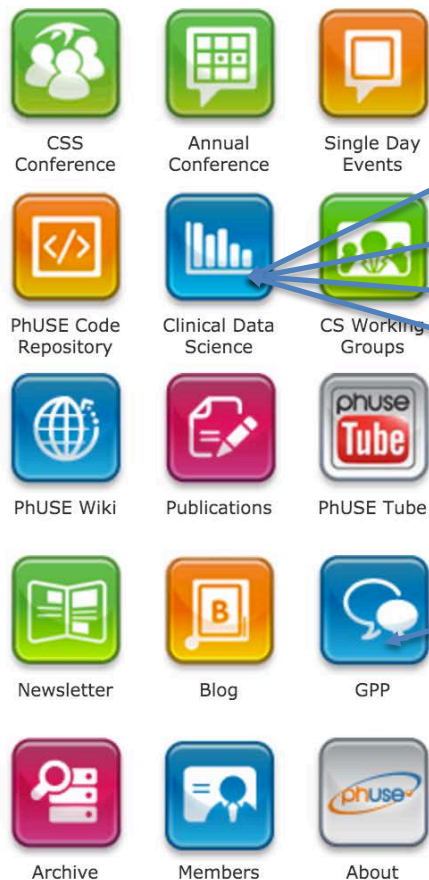
Available on the
App Store



Android app on
Google Play



Location of “working groups”



CSS Working Groups

Data Transparency

Future Forum

KPIs

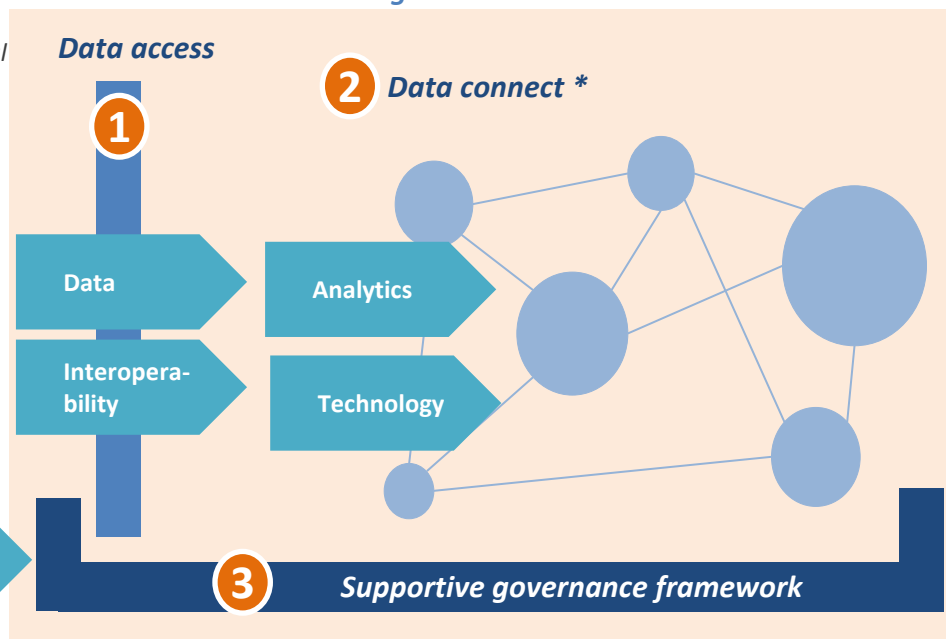
Good Programming Practice

<http://www.phuse.eu/cs-working-groups.aspx>

PhUSE Future Forum - Enabling adaptability and flexibility that will bring more value

PhUSE FUTURE FORUM Strategic Initiatives

- Standardisation & uniformisation / optimal use of data standards
- Data transparency
- Data sharing and interoperability
- Improve access to & re-use of data, improve quality of data
- Improve access to patients, target groups of patients, pathology orientation



- Build expertise networks
- Share best practices & know-how
- Novel trial designs
- New technologies
- Getting more out of data
- Appropriateness: data fit for purpose (right data for the question)

* White House \$400b for 5G

- Collaborative business models
- Facilitate access to innovative therapeutic solutions
- Provide supportive incentives for innovation
- Interdisciplinary & multidisciplinary approaches

PhUSE Data Transparency Workgroups

- 4 Workgroups
 - EMA Policy 0070
 - De-identifying ADaM data
 - Complexities around de-identified partial dates
 - **Risk assessments** on de-identified data



New for
2016!

EMA Policy 0070

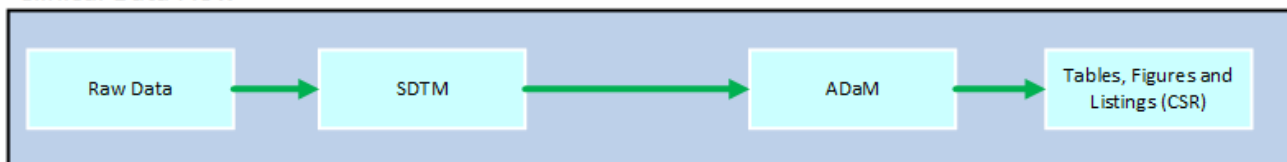
- External guidance on the implementation of the EMA policy on the publication of clinical data for medicinal products for human use
- Released March 2nd, 2016
- Provides detailed guidance on document redactions

ADaM De-identification

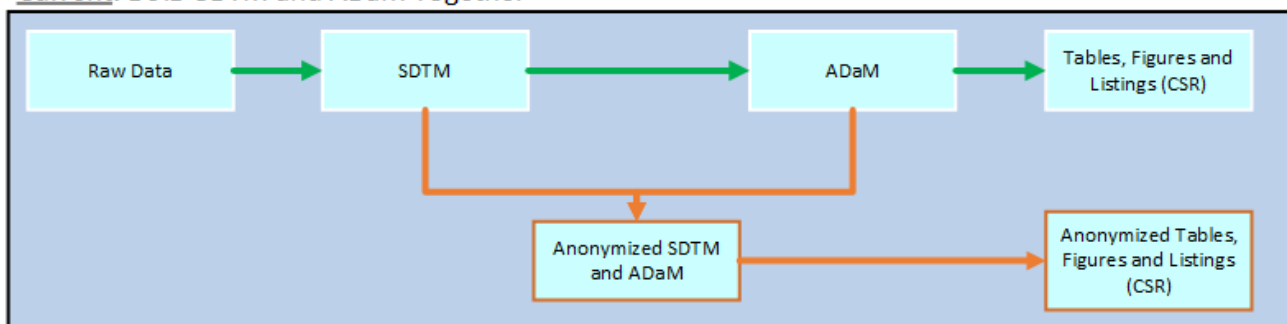
- Standards are still being developed
- Expected release this year
- Existing SDTM 3.2 De-identification standards
 - [http://www.phuse.eu/Data Transparency downloads/ad.aspx](http://www.phuse.eu/Data_Transparency_downloads/ad.aspx)
- Various process scenarios are still being worked out

De-Identification Scenarios

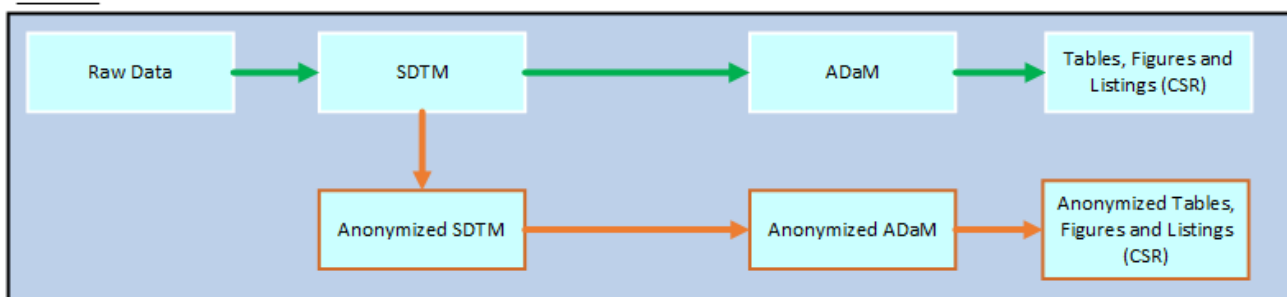
Clinical Data Flow



Current: DeID SDTM and ADaM Together



Future: DeID at SDTM



→ Clinical Data Analysis Code → Anonymization Code

ADaM De-identification

- Handling partial dates different than in SDTM
- Three common practices are being evaluated
 - Imputed using offset SDTM partial dates
 - Setting imputed ADaM dates (+flags) to missing
 - Only using relative days instead of date fields

Risk Assessment

- Grey area due to lack of guidance and expertise
- Looking at initial recommendations about risk to develop more comprehensive guidance
- EMA's [guidance](#) about risk assessment in semi-public context vs. controlled data sharing is a major driver

Looking Ahead: 2016 Single Day Events

	  	Beijing, China - 8th July Deerfield, IL - 21st July Trivandrum, India - 30th July
	 	Frenchtown, NJ - 4th August Tokyo, Japan - 4th August
	 	Shanghai, China - 4th November Durham, NC- 10th November
		Mumbai, India - 3rd December

2016 Annual Conference

Annual Conference



Barcelona 2016

Fast Track to Approval: Speed and Efficiency

9th-12th October Princessa Sofia Gran Hotel, Barcelona

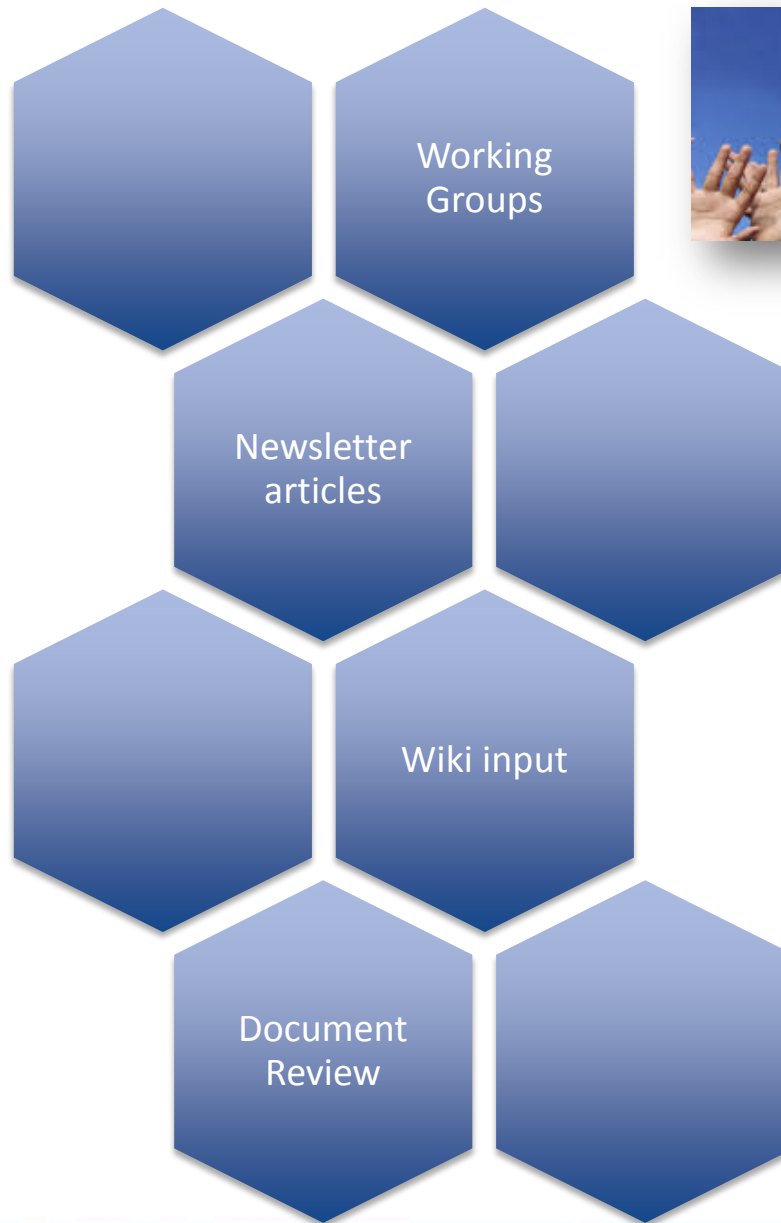
Annual Conference 2016

Fast Track to Approval: Speed and Efficiency

9th - 12th October 2016

****Registration Opens 1st March****





WE NEED YOU !





The premier community for people working in the biometric area



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